U.S. FOOD & DRUG ADMINISTRATION

May 10, 2022

Brian Ciccariello
Quanterix Corporation
900 Middlesex Turnpike, Building One
Billerica, MA 01821

Re: Revocation of EUA202912

Dear Brian Ciccariello:

This letter is in response to a request from Quanterix Corporation, received May 5, 2022, and May 9, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the Simoa SARS-CoV-2 N Protein Antigen Test issued on January 5, 2021, and reissued on September 10, 2021, and December 21, 2021. FDA understands that Quanterix Corporation discontinued distribution of their Simoa SARS-CoV-2 N Protein Antigen Test and there are no viable (non-expired) tests remaining.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Quanterix Corporation has notified FDA that Quanterix Corporation has discontinued distribution of the authorized product and requested FDA withdraw the authorization of the Simoa SARS-CoV-2 N Protein Antigen Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202912 for the Simoa SARS-CoV-2 N Protein Antigen Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Simoa SARS-CoV-2 N Protein Antigen Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13639 Filed 6–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 27, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information

collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is Pilot Survey to Develop Standardized Reporting Forms for Federally Funded Public Health Projects. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

OMB Control Number 0910–NEW

This information collection supports federally funded public health projects administered by the Agency's Office of Regulatory Affairs (ORA). As part of FDA's efforts to protect the public health, we work collaboratively with State partners to enhance oversight of FDA-regulated products. Consistent with applicable regulations pertaining to federally funded programs, we currently collect information related to an awardee's progress in completing agreed-upon performance metrics 3 to 4 times a year during the reporting period. Respondents to the information collection are recipients of FDA-funded projects who submit required information to FDA in free text and narrative form via portable document format. To increase our efficiency in evaluating program effectiveness and return-on-investment (ROI)/return-on-value (ROV) for the federally funded projects that we administer, we intend to develop and establish the use of digital forms that contain standardized questions to capture data elements necessary to measure/track ROI/ROV. We believe the use of standardized forms will reduce the time required by awardees in completing and submitting progress reports.

As part of the pilot, respondents will complete an initial report and progress/performance reports, which include data fields to identify the award project and contact person and directs specific questions to respondents regarding project and progress updates. Based on public feedback, we hope to revise the reports, tailoring for project specificity and purpose, to include, but not limited to, improvements, such as drop-down menu selections and potential common response indicators that will reduce time for respondents and allow us to more quickly process information and determine impacts at the Agency level. As information will be requested of actively funded projects, it may become necessary to request additional information for a particular project to complete the performance evaluation(s) in a timely manner. To ensure data is sufficient, on a case-by-case basis, FDA anticipates a need for followup questionnaire(s) to supplement the progress reports as instruments of collection are developed and fine-tuned through this effort.

In the **Federal Register** of July 29, 2021 (86 FR 40853), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Awardee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Report	400	1	400	10	4,000
Updated Reports	400	2	800	40	32,000
Supplement or Followup Report (if applicable)	100	1	100	10	1,000
Total					37,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that 400 respondents will participate under this pilot project and will submit an average of 3 to 4 reports within a single budget year (table 1). To ensure adequate reporting will be achieved over the course of this pilot, the option for a supplement or followup report is included in the estimated reporting burden; however, the need for these reports will be determined on a case-by-case basis with the FDA project manager.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Awardee activity	Number of recordkeepers	Records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records related to Initial Report	400	1	400	0.5 hour (30 minutes) ..	200
Records related to Updated Reports	400	2	800	0.5 hour (30 minutes) ..	400
Records related to Supplement or Followup Report (if applicable).	100	1	100	0.5 hour (30 minutes) ..	50
Total					650

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the project and compiling reports. Respondents should use current record retention capabilities for electronic or paper storage to achieve these activities. We assume it will take 0.5 hour/year to ensure the documents related to submitting a request to participate in the program are retained properly according to their existing recordkeeping policies,

but no less than 3 years, as recommended by FDA (table 2).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Awardee activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with partnering entities related to Initial Report	300	2	600	8	4,800
Coordination with partnering entities related to Updated Reports	300	4	1,200	8	9,600
Coordination with partnering entities related to Supplement or Followup Report (if applicable)	100	2	200	8	1,600
Total					16,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. We estimate that 300 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. We assume each respondent will spend 8 hours coordinating with each partnering entity on each response for this pilot. We estimate that seven respondents will need to coordinate with an average of two partnering entities to create updated reports and the final report to submit to FDA (table 3).

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13642 Filed 6–24–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application for ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasesPriorityVoucherProgram/default.htm.* For further information about ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, go to the ''*Drugs@FDA*'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13628 Filed 6–24–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public via webcast. For this meeting, the TBDWG will review the first draft of chapters for the report and further discuss plans for developing the next report to the HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 and 2020 report. The 2022 report will address a wide range of topics related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify advances made in research, as well as overlap and gaps in tick-borne disease research; and provide recommendations regarding any appropriate changes or improvements to such activities and research.

DATES: The public can view the meeting online via webcast on July 19–20, 2022 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change) each day. The confirmed times and agenda items for the meeting